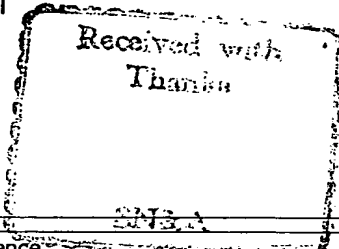


PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

Date of mailing
(day/month/year)

04.10.2004- 03.12.04

Applicant's or agent's file reference
SUVN-RK-004

IMPORTANT NOTIFICATION

International application No.
PCT/IN 03/00223

International filing date (day/month/year)
19.06.2003

Priority date (day/month/year)
21.06.2002

Applicant
SUVEN LIFE SCIENCES LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference SUVN-RK-004	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/N 03/00223	International filing date (day/month/year) 19.06.2003	Priority date (day/month/year) 21.06.2002
International Patent Classification (IPC) or both national classification and IPC C07D487/04		
Applicant SUVEN LIFE SCIENCES LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 43 sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 19.01.2004	Date of completion of this report 04.10.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Boletti-Cremers, K Telephone No. +49 89 2399-8541 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/IN 03/00223**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

4, 15, 17, 18 as originally filed
16 received on 24.05.2004 with letter of 22.05.2004
1-3, 5, 6, 6A, 7-12, 12A, 13, 14, received on 20.09.2004 with letter of 09.09.2004
19, 20-37

Claims, Numbers

1-22 received on 20.09.2004 with letter of 09.09.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/IN 03/00223**

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-22 , with proviso that an acceptable formulation of the claims could be provided in the regional proceedings to come.
	No: Claims	
Inventive step (IS)	Yes: Claims	1-22, with the same proviso as for the novelty .
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations

see separate sheet

Point I. - Lack of support and Clarity of the amendments.

1.1 Although most of the claims on file are the result of a drastic restriction of the original claims, some amendments cannot find a clear and unambiguous support in the original application as filed.

Indeed as now on file the side chain located on the position 11 of the (I) compounds refers to a repeated motive where n can either be 1 or 2.

Although the original filed matter and all the examples refer unambiguously to a value of 1 for n , there is no support for the value of n being 2, which now contravenes the requirements of Art 34 (2) (b), last sentence PCT.

Either the value of $n : 2$ should be deleted from the application, or the Applicant is invited to point out from the original application as filed and in the regional proceedings to come, where a possible, clear and unambiguous descriptive support exists for the value $n : 2$.

1.2 Previous point I of the preliminary opinion (see point I of 21.06.2004) is set aside in view of the reformulations and replaced by present point I.

POINT V.

The following documents, quoted in the I.S.R., have been considered as relevant for the examination of the present application. Their numbering will be adhered to for the rest of the procedure.

- (1) Bioorganic & Medical Chemistry Letters 2001, 11(9),1237-1240.
- (2) WO-A-0076521.
- (3) WO-A-9300334.
- (4) US-B1-6465660 (Point VI).

1. Novelty.

1.1 Since, according to the definitions of the claimed compounds, when $n:1$ and both R_{11} and R_{12} are an oxo radical, the claimed compounds should be -amido-methylene substituted- and not amido ethylene as in (1), and in view of the fact that, provided $n: 2$ could be acceptable in the regional proceedings to come, the claimed compounds should be a radical - $R_9 R_{10}-(C-R_{11}R_{12})_n-NR_{13} R_{14}$ of the type $-CH_2-(CO-CO)-NR_{13} R_{14}$ (if $R_9 R_{10}$ is methylene, of course), the claims on file are novel with respect to the content of (1). Moreover, since the compounds disclosed

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IN 03/00223

in (3) are not isoindolones , but isoindoles compounds , the claimed matter can also be regarded as novel with respect to the content of (3).

- 1.2 In view of the fact that the compounds disclosed in (2) are not tetracyclic isoindolo(2,1-a)indolone compounds , the novelty of the claims with respect to the content of (2) is acknowledged.
- 1.3 Whether the content of (4) , as published on 15.10.2002, is relevant for the examination of the novelty and the inventive step of the claimed matter will only be investigated in the European regional phase and will essentially depend on the examination of validity of the priority rights claimed by present invention , which at present is not possible. Although (4) is not prior art according to the Chap II PCT proceedings, its content does not affect the novelty of the claims on file because it lacks the side chain located on position 11 of the isoindolo(2,1-a)indolone compound

2. Inventiveness.

Since there is no logical structure- activity relationship between the claimed compounds and those disclosed in (1) and (3), the claimed matter can be regarded as inventive with respect to the prior art.

3. Formal Point .

- 3.1 Documents (1) and (3) should be mentioned and briefly discussed in the description when the application will enter the regional proceedings to come.